

**Appln No. 10/660,815**  
**Amdt date September 4, 2007**  
**Reply to Office action of June 14, 2007**

### **REMARKS/ARGUMENTS**

Claims 1-16, 18-25, 27, and 30-33 are pending in the above-referenced application.

Claim 32 has been amended; claims 34 to 45 have been cancelled and claims 46 to 52 have been added as indicated above to further define Applicant's invention.

This is a response to the Office Action dated June 14, 2007 wherein the Examiner objected to claims 32 and 33 for lack of antecedent basis and rejected: (1) claims 1-9, 16, 18-22, 24-25, 27, 30 and 32-33 under 35 U. S. C. 103(a) as being obvious over U.S. Patent No. 6,974,447 (Smith et al.); (2) claims 10-15 under 35 U. S. C. 103(a) as being unpatentable over Smith ('447) in view of U.S. Patent No. 6,846,305 (Smith et al.); and (3) claims 23 and 31 under 35 U. S. C. 103(a) as being unpatentable over Smith ('447), as applied to the rejection of claim 1, in view of U. S. Patent No. 6,280,431 (Domkowski et al.).

In view of the amendments indicated above and the remarks that follow, reconsideration and a notice of allowance are respectfully solicited.

### **Interview Summary**

A telephone interview was conducted on August 10, 2007 between Examiner Chapman and Tom Dao, attorney for the Applicant. During the telephone interview, Applicant rectified an incorrect statement previously made to the Examiner with respect to ownership of the U.S. patent 6,974,447 by Smith et al. and confirmed that the '447 patent is not owned by the assignee B. Braun Medical Inc.

Two main topics were addressed during the interview. First, Applicant discussed the option of adding new claims, which are similar to the ones that are being restricted but which are broadly recited to cover both the elected and non-elected claims. The Examiner acknowledged the option of adding generic claims but would not commit to an agreement without further consideration, although the Examiner could not cite to an MPEP or a CFR section that would bar such addition other than it would take her more time to examine the claims. Second, differences between the instant claims and Patent No. 6,974,447 to Smith et al were discussed. Comparing figures 2, 4 and 4A of the instant application and figures 1A and 2A of the cited reference,

**Appln No. 10/660,815**  
**Amdt date September 4, 2007**  
**Reply to Office action of June 14, 2007**

Applicant pointed out that Smith does not disclose or contemplate an attachment flange with interior surfaces that contact one another as recited by the rejected claims. The Examiner acknowledged the differences but would not commit to an allowance without further consideration.

#### Claim Objections

Claim 32 has been amended as indicated above to overcome the lack of antecedent basis objection. Removal of the objection is respectfully requested.

#### §103(a) Rejection of Claims 1-9, 16, 18-22, 24-25, 27, 30, and 32-33 by '447 Smith et al.

In rejecting claims 1-9, 16, 18-22, 24-25, 27, 30, and 32-36 under §103(a) as being obvious over the '447 Smith patent, the Examiner contends that Smith disclosed the main elements and limitations of the rejected claims including:

"...a receptacle, that is a flexible bag, made of a flexible front sheet sealed to a flexible back sheet and having at least one port, which is a nozzle, molded to the bag at an attachment point seen to be an attachment flange. The attachment flange is part of the bag and therefore has a first and a second layer joined together. The attachment flange has a first opening and a second, larger opening and comprises a fin (120) (see figures 5-8)."

The Examiner concludes that it would have been obvious to one having ordinary skill in the art to modify Smith's attachment flange to have its two ends larger than the internal diameter of the nozzle, as recited by independent claim 1.

Preliminarily, Applicant reminds the Examiner that to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second,

there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. MPEP 706.02(j).

Claim 1 recites a flexible container comprising: a flexible front sheet and a flexible rear sheet attached to one another along at least one edge, a container port comprising a nozzle, which has an internal diameter, integrally molded to an attachment flange, which is disposed between the flexible front sheet and flexible rear sheet; wherein the attachment flange comprises two ends and a first attachment flange layer comprising an interior surface and an exterior surface and a second attachment flange layer comprising an interior surface and an exterior surface attached to one another along at least one edge, which is located at one of the two ends, a center section located between the two ends; and wherein the two interior surfaces are spaced apart from one another at the center section and converge at the two ends, and wherein a distance measured between the two ends at a point spaced apart from the container port is larger than the internal diameter of the nozzle.

Thus, claim 1 clearly recites, in part, a flexible container comprising "a nozzle. . . integrally molded to an attachment flange, which is disposed between the flexible front sheet and flexible rear sheet; wherein the attachment flange comprises . . . a first attachment flange layer comprising an interior surface and an exterior surface and a second attachment flange layer comprising an interior surface and an exterior surface attached to one another along at least one edge, which is located at one of the two ends, a center section located between the two ends; and wherein the two interior surfaces are spaced apart from one another at the center section and converge at the two ends".

The '447 Smith patent discloses a container for a therapeutic fluid susceptible to deterioration on exposure to a gas such as oxygen or carbon dioxide (ABSTRACT). As shown in Figure 1A, Smith discloses a container having a port tube 52 attached directly to the front and rear sheets of the container. The port tube 52 may be formed from a multi-laminate structure (FIGs. 2a and 2b) and is round in all embodiments shown and described, i.e., without an edge or

an end and clearly not an attachment flange. The tube also has a uniform diameter with each of the two ends of the tube having similar sized diameter. Because the port tube 52 is in fluid communication with the internal cavity of the bag 10, a closure 54 is used to seal the port end 116 of the port tube 52 (FIGs. 4 and 8). Finally, a spike holder 50 (FIGs. 5 and 6) is attached to the port tube 52 with the first chamber 110 (FIG. 5) placed over the end portion 116 of the port tube 52 (FIG. 8). The second chamber 112 of the spike holder 50 "is dimensioned to have an interference fit with an access spike or transfer needle 117..." (Col. 9:29-31). In short, with reference to the left side of FIG. 8, the port tube 52 is attached directed to the front and rear sheets of the flexible container and no attachment flange other than the tube is used.

The part that the Examiner refers to as an "attachment flange" in her description of "...The attachment flange is part of the bag and therefore has a first and a second layer joined together. The attachment flange has a first opening and a second, larger opening and comprises a fin (120) (see figures 5-8)" is in fact described in the '447 Smith patent as a spike holder 50 (Fig. 5) comprising a flange. As described by Smith at col. 9:43-48:

..the spike holder 50 has an outwardly extending flange 118 at an intermediate portion thereof. The flange 118 is positioned generally at the intersection of the first chamber 110 and the second chamber 112. The flange 118 has a first surface 120 which is textured to facilitate handling and manipulation of the holder. (Emphasis added).

As shown in Fig. 1A, the spike holder 50, which is connected to the port tube 52 at an end furthest away from the container 30, clearly is not "disposed between the flexible front sheet and flexible rear sheet" of the container 30, as recited by claim 1. Thus, among other things, nowhere did Smith disclose a container comprising "a nozzle, which has an internal diameter, integrally molded to an attachment flange, which is disposed between the flexible front sheet and flexible rear sheet; wherein the attachment flange comprises two ends and a first attachment flange layer comprising an interior surface and an exterior surface and a second attachment

**Appln No. 10/660,815**  
**Amdt date September 4, 2007**  
**Reply to Office action of June 14, 2007**

flange layer comprising an interior surface and an exterior surface attached to one another along at least one edge, which is located at one of the two ends, a center section located between the two ends; and wherein the two interior surfaces are spaced apart from one another at the center section and converge at the two ends".

In view of the foregoing, Applicant respectfully submits that Smith fails to teach or suggest all the claim limitations as required by MPEP 706.02(j); and therefore fails to render claim 1 obvious under §103(a). No matter how the container disclosed by Smith is manufactured, it does not incorporate or teach a container port having an attachment flange as recited by claim 1. Reconsideration and a notice of allowance are respectfully requested.

Because 2-9, 16, 18-22, 24-25, 27, 30, and 32-33 depend, either directly or indirectly, from claim 1, they too are allowable over the '447 Smith reference for at least the same reasons as claim 1.

§103(a) Rejection of Claims 10-15 by

'447 Smith et al. patent in view of Smith et al. patent (US 6,846,305)

In rejecting claims 10-15, the Examiner contends that the '447 Smith reference disclosed essentially as claimed but does not disclose a bag with distinct film layers or a port made from a blend of polypropylene-ethylene random copolymer and SEBS elastomer. The Examiner then relied on the '305 Smith reference to make up for the shortcomings and considered the two references obvious to combine. As further discussed below and without conceding that the two references are combinable, compatible, not teach away from one another, or are defective in other ways, Applicant submits that the combination failed to render claims 10-15 obvious.

Claims 10-15 are dependent claims and depend from claim 1. Because the '305 Smith reference is not relied on to show nor does it disclose a nozzle, which has an internal diameter, integrally molded to an attachment flange, which is disposed between the flexible front sheet and flexible rear sheet; wherein the attachment flange comprises two ends and a first attachment flange layer comprising an interior surface and an exterior surface and a second attachment flange layer comprising an interior surface and an exterior surface attached to one another along

**Appln No. 10/660,815**  
**Amdt date September 4, 2007**  
**Reply to Office action of June 14, 2007**

at least one edge, which is located at one of the two ends, a center section located between the two ends; and wherein the two interior surfaces are spaced apart from one another at the center section and converge at the two ends, the '305 Smith reference does not make up for the deficiencies of the '447 Smith reference. Accordingly, because the combination failed to render claim 1 obvious, it also failed to render claims 10-15 obvious.

§103(a) Rejection of Claims 23 and 31 by '447 Smith et al. patent in view of Domkowski et al.

In rejecting claims 23 and 31, the Examiner contends that the '447 Smith et al. reference disclosed essentially as claimed but does not disclose a port having a film innerseal affixed to the port or an attachment flange having a pyramid shape. The Examiner then relied on the '431 Domkowski reference to make up for the shortcomings and considered the two references obvious to combine. As further discussed below and without conceding that the two references are combinable, compatible, not teach away from one another, or are defective in other ways, Applicant submits that the combination failed to render claims 23 and 31 obvious.

Claims 23 and 31 depend from claim 1. Because the '431 Domkowski et al. reference is not relied on to show nor does it disclose a nozzle, which has an internal diameter, integrally molded to an attachment flange, which is disposed between the flexible front sheet and flexible rear sheet; wherein the attachment flange comprises two ends and a first attachment flange layer comprising an interior surface and an exterior surface and a second attachment flange layer comprising an interior surface and an exterior surface attached to one another along at least one edge, which is located at one of the two ends, a center section located between the two ends; and wherein the two interior surfaces are spaced apart from one another at the center section and converge at the two ends, Domkowski does not make up for the deficiencies of Smith. Accordingly, because the combination failed to render claim 1 obvious, it also failed to render claims 10-15 obvious.

**NEW CLAIMS 46-52**

**Appln No. 10/660,815**  
**Amdt date September 4, 2007**  
**Reply to Office action of June 14, 2007**

Claims 46-52 have been added to further define Applicant's invention. Of the added claims, claims 46 and 50 are independent claims. Both claims 46 and 50 recite a flexible container comprising a port attached to an attachment flange, which is then attached to a front sheet and a rear sheet of the container.

In the Response to Restriction Requirement dated April 19, 2007, Applicant had selected Group H, FIGs. 1 and 17 to prosecute. Applicant submits that claims 46 and 50 are generic and read on FIGs. 1 and 17. Furthermore, claims 46 and 50 share similar elements and limitations as claim 1, which were discussed extensively above in distinguishing over the '447 Smith reference.

Applicant further submits that unlike what the Examiner has alleged<sup>1</sup> in the Office Action, elements and limitations recited in independent claims 1, 46, and 50 can all be found in Group H, FIGs. 1 and 17.

In comparison to the '447 Smith reference, Applicant submits that independent claims 46 and 50 are patentable over Smith as they both recite an attachment flange that Smith does not teach or contemplates.

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<sup>1</sup> "one claim recites limitations that under the disclosure are found in a first species but not in a second, while a second claim recites limitations disclosed only for the second species and not the first."

**Appln No. 10/660,815**

**Amdt date September 4, 2007**

**Reply to Office action of June 14, 2007**

In view of the foregoing remarks, the Application is thought to be in condition for allowance and early notice thereof is respectfully solicited.

Should the Examiner find it necessary to speak with Applicant's attorney, she is invited to contact the undersigned at the telephone number identified below.

Respectfully submitted,

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